Development of TriLeukeVax, an Engineered Autologous Leukemia Vaccine for Stimulating Cytolytic Immune Responses to Residual Leukemic Stem Cells

Grant Award Details

Development of TriLeukeVax, an Engineered Autologous Leukemia Vaccine for Stimulating Cytolytic Immune Responses to Residual Leukemic Stem Cells

Grant Type: Late Stage Preclinical Projects

Grant Number: CLIN1-13985

Investigator:

Name:	Karin Gaensler
Institution:	University of California, San Francisco
Type:	PI

Award Value: $6,000,000

Status: Pre-Active

Grant Application Details

Application Title: Development of TriLeukeVax, an Engineered Autologous Leukemia Vaccine for Stimulating Cytolytic Immune Responses to Residual Leukemic Stem Cells

Public Abstract:

Therapeutic Candidate or Device

TriLeukeVax, an autologous AML vaccine designed to stimulate induction of anti-leukemic cytolytic activity and improve relapse free survival (RFS).

Indication

Older leukemia patients who achieve remission with chemotherapy and are at high risk of relapse, but are not eligible for allogeneic transplantation

Therapeutic Mechanism

Most older patients with acute myelogenous leukemia (AML) have dismal outcomes due to the persistence of residual AML cells. These residual cells are the cause of relapse that results in poor overall survival. To increase relapse free survival, patient's AML cells are engineered to express a novel combination of immune-stimulatory proteins that stimulate the patient's immune system to kill residual AML. Irradiated, engineered AML would be injected as a vaccine after chemotherapy is complete.

Unmet Medical Need

Most patients with AML are over 60 yo. Despite chemotherapy, patients usually relapse. Although allogeneic transplantation improves outcomes, many older patients are ineligible due to co-morbidities. Thus, there is an unmet need for safe and effective treatments to improve relapse-free survival

Project Objective

IND submitted, begin clinical start-up activities

Major Proposed Activities

- Generate 3 clinical scale vaccine batches meeting release criteria and complete safety studies including RCL testing and growth inhibition assays
- Toxicology studies by serial vaccination of mice with murine version of TriLeukeVax, potential drug product hazard study in immune deficient mice,
- Obtain clinical Lentivirus prep with titer, identity, sterility, etc. assays completed; File IND with trial design; begin clinical start-up activities

Statement of Benefit to California:

In AML, curative therapy usually requires inpatient hospitalization with relocation of patients to urban centers, away from their communities. Historically, certain populations have had more limited access to translational and clinical research studies resulting in a lack of diversity and inclusion. Because TriLeukeVax is a universally applicable immunotherapy, our plan is to make the vaccine widely accessible in California through the UC Hematological Malignancies Consortium

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